



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,933	04/15/2004	James R. Braig	OPTIS.100A	7558
20995 7590 10/09/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER AKANBI, ISIAKA O	
			ART UNIT 2886	PAPER NUMBER
			NOTIFICATION DATE 10/09/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

## Office Action Summary

Application No.

10/824,933

Applicant(s)

BRAIG ET AL.

Examiner

Isiaka O. Akanbi

Art Unit

2886

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: 2 August 2007.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 September 2007 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Sterling et al. (2003/0090649 A1).

As regard to claims 1 and 46, Sterling discloses a reagentless sample element comprising of the following:

first and second (figs. 15-16A: 360,350) substantially parallel faces, the parallel faces at least partially defining a sample chamber configured to hold a volume of fluid, the sample chamber being reagentless;

an optical path extending through the parallel faces and the sample chamber, such that electromagnetic radiation can propagate through the sample chamber (figs. 20A, 24A:

Art Unit: 2886

335)(pars. 0010-0012); Sterling further discloses a reagent/coating/compound (i.e. polished gold coating) that is disposed in the optical path (inner surface coating material (i.e. gold coating))(pars. 0092- 0093) that perform or function as an optical key and thus meeting the limitations of "an optical key for qualifying the sample element for use with a particular analyte detection system, the optical key comprising:

an identifying compound disposed in the optical path; at least a portion of a spectral scan of the identifying compound stored in the analyte detection system (fig. 1: 30)(see abstract)(pars. 0010 and 0013); the identifying compound having at least one indexed optical absorbance feature, such that the spectral scan generated by electromagnetic radiation propagated through the identifying compound yields the indexed optical absorbance feature, the identifying compound being disposed within or on at least one of the parallel faces and separated from the sample chamber such that the identifying compound does not intermingle with the sample fluid"; (figs. 15-16A)(see abstract)(pars. 0158-0172) and Sterling further teaches the identifying compound that is based on a sample element parameter (i.e. reflectivity, transmissivity) that affects the accuracy of analyte concentration readings (pars. 0011, 0092).

As to claim 2, according to claim 1, Sterling discloses wherein the first and second substantially parallel faces are at least partially transmissive to electromagnetic radiation (par. 0162).

As to claims 3 and 4, Sterling discloses wherein the parallel faces are at least partially transmissive to infrared electromagnetic radiation and wherein the indexed optical absorbance feature is adjacent to or overlapping an absorbance feature of an analyte detectable by the analyte detection system (pars. 0064, 0066)(figs. 13-18A).

As to claims 5 and 6, Sterling discloses wherein the analyte detectable by the analyte detection system is glucose and the indexed optical absorbance feature is an absorbance maximum or an absorbance minimum (i.e. appropriate level)(par. 0005).

As to claim 7, Sterling discloses wherein the identifying compound is a hydrocarbon (par. 0065).

As to claim 8, Sterling discloses wherein the identifying compound is a coating on at least a portion of the sample element (pars. 0073, 0076-77 and 0092).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-12, 31-37, 40-44 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Jina et al. (5,526,120).

Regarding to claims 9, 31-33, 40, 42-44 and 47, Jina discloses a sample element that is verifiable as approved for use with a detection system comprising of the following:

an optical path (fig. 2: 30) for determining analyte concentration (col. 1, line 7-11); and an identification key (figs. 1, 4, 4a and 5: 56,58, 62) in the optical path for verifying that the sample element (figs. 1, 4, 4a and 5: 10, 46 and 60), is approved (i.e. by having appropriate detection means)(col. 12, line 46-67), the identification key comprising a physical property (i.e. shape) of the sample element (col. 6, line 40-43)(col. 13, line 7-25); receiving (14) the sample element (10) in an analyte detection system; after receiving, emitting radiation along an optical path, the optical, path for determining analyte concentration; qualifying the sample element by determining whether the sample element is of a type which is suitable for use with the analyte detection system (12), if the sample element is of a type which is suitable for use with the analyte detection system, analyzing an optical property of the material sample (and if the sample element is not of a type which is suitable for use with the analyte detection system, refusing to analyze an optical property of the material sample (figs. 1, 4-12)(col. 6, line 40-43)(col. 12, line 12-col. 14, line 1-5).

As to claim 10, Jina also discloses wherein the physical property is an optical absorption of a window (fig. 2: 11, 30) in the optical path (col. 7, line 30-33).

As to claims 11 and 12, Jina also discloses sample element that is characterized by physical property that is a thickness of a window in the optical path and wherein the physical property is a thickness of sample chamber in the optical path (figs. 7-12).

As to claim 34, Jina also discloses wherein qualifying the sample element comprising measuring an optical absorbance spectrum of the sample element and analyzing the measured optical absorbance spectrum for a qualifying absorbance feature (col. 1, line 6-11).

As to claim 35, Jina further discloses wherein the qualifying absorbance feature is an absorbance maximum or an absorbance minimum (col. 3, 38-col. 4, line 1-2).

As to claim 36, Jina also discloses wherein qualifying the sample element comprises reading at least one datum from an identification medium (col. 4, line 48-54).

As to claim 37, Jina also discloses wherein qualifying the sample element further comprising checking whether the datum corresponds to a datum stored in the analyte detection system (col. 3, line 39-47).

As to claim 41, Jina also discloses a reagentless sample chamber (i.e. period before introducing reagent/sample/analytes into chamber) in said optical path.

Claims 14-18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. (5,962,215).

As regard to claims 14 and 48, Douglas discloses a sample element for use with an analyte detection system comprising of the following:

a sample chamber (fig. 1: 49) and an identification key (figs. 1 and 3B)(col. 16, line 2-15)(col. 17, line 52-55)(col. 19, line 10-28) or (i.e. hydrophilic material)(coating material) that is located within or on the sample element in an optical path for analyte measurement, the identification key configured to indicate to the analyte detection system a qualification state of the sample element (col. 11, line 5-8)(col. 12, line 54-col. 13, line 9)(col. 15, line 39-62)(col. 23, line 49-67).

As to claim 15, Douglas also discloses wherein the identification key is configured to indicate a qualification state in which the sample element is configured for use with the analyte detection system (col. 16, line 7-15).

As to claims 16 and 17, Douglas further discloses wherein the identification key (61/101) comprising a compound (Barcode on strip) having an optical absorbance spectrum with a

qualifying optical absorbance feature and wherein the qualifying optical absorbance feature is adjacent to or overlapping an absorbance feature of an analyte detectable by the analyte detection system (72)(figs. 1-3)(col. 24, line 36-47).

As to claim 18, Douglas also discloses wherein the analyte detectable by the analyte detection system is glucose (col. 1, line 13-14).

As to claim 21, Douglas also discloses wherein the identification key (61/101) has a structure configured to mechanically engage a complimentary structure in the analyte detection system, such that mechanical engagement of the sample element with the analyte detection system indicates to the analyte detection system a qualification state of the sample element in which the sample element is configured for use with the analyte detection system (fig. 3B)(col. 16, line 6-15).

As to claim 45, Douglas also discloses a reagentless sample chamber (i.e. period before introducing reagent/sample/analytes into chamber) in said optical path.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterling et al. (2003/0090649 A1) in view of Hillman et al. (4,963,498).

Regard to claims 1 and 46, Sterling teaches of a reagentless sample element comprising first and second (figs. 15-16A: 360,350) substantially parallel faces, the parallel faces at least partially defining a sample chamber configured to hold a volume of fluid; the sample chamber being reagentless;

an optical path extending through the parallel faces and the sample chamber, such that electromagnetic radiation can propagate through the sample chamber (figs. 20A, 24A: 335)(pars. 0010-0012); and

an optical key (i.e. polished gold coating) for qualifying the sample element for use with a particular analyte detection system, the optical key comprising:

an identifying compound disposed in the optical path (inner surface coating material (i.e. gold coating)(pars. 0092- 0093); at least a portion of a spectral scan of the identifying compound stored in the analyte detection system (fig. 1: 30)(see abstract)(pars. 0010 and 0013); the identifying compound (i.e. blood components) having at least one indexed optical absorbance feature, such that the spectral scan generated by electromagnetic radiation propagated through the identifying compound yields the indexed optical absorbance feature, the identifying compound being disposed within or on at least one of the parallel faces and separated from the sample chamber such that the identifying compound does not intermingle with the sample fluid (figs. 15-16A)(see abstract)(pars. 0158-0172) and Sterling further teaches the identifying compound that is based on a sample element parameter (i.e. reflectivity, transmissivity) that affects the accuracy of analyte concentration readings (pars. 0011, 0092).

Sterling fails to specifically specify that the (i.e. polished gold coating) is an optical key for qualifying the sample element for use with a particular analyte detection system.

However, the use of coating to qualifying a sample element for use with a particular analyte detection system is known in the art, as evidenced by Hillman (col. 2, line 50-55)(col. 3, line 65-col. 4, line 1)(col. 5, line 67-col. 6, line 5)(col. 6, line 60-67).

Thus, it would have been at least obvious to one having ordinary skill in the art at the time of invention was made to provide an optical key (i.e. polished gold coating) for qualifying



the sample element for use with a particular analyte detection system for the purpose of providing a more accurate measurement.

As to claim 2, Sterling also discloses the limitations wherein the first and second substantially parallel faces are at least partially transmissive to electromagnetic radiation (par. 0162).

As to claims 3 and 4, Sterling further discloses wherein the parallel faces are at least partially transmissive to infrared electromagnetic radiation and wherein the indexed optical absorbance feature is adjacent to or overlapping an absorbance feature of an analyte detectable by the analyte detection system (pars. 0064, 0066)(figs. 13-18A).

As to claims 5 and 6, Sterling also discloses wherein the analyte detectable by the analyte detection system is glucose and the indexed optical absorbance feature is an absorbance maximum or an absorbance minimum (i.e. appropriate level)(par. 0005).

As to claim 7, Sterling also discloses wherein the identifying compound is a hydrocarbon (par. 0065).

As to claim 8, Sterling also discloses wherein the identifying compound is a coating on at least a portion of the sample element (pars. 0073, 0076-77 and 0092).

Claims 13 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jina et al. (5,526,120) in view of Douglas et al. (5,962,215).

As to claim 13, Jina fails to specify that the physical property is a background optical absorbance spectrum of the optical path.

However, providing appropriate calibration data that includes physical property (i.e. physical background optical absorbance spectrum) is known in the art, as evidenced by Douglas teaches of calibration (col. 6, line 45-53)(col. 16, line 7-15).

Therefore it would have been at least obvious to one having ordinary skill in the art at the time of the invention was made to modify Jina by incorporating a background that is optical absorbance spectrum of the optical path for the purpose of providing a more accurate measurement or calibration, as per the teachings of Douglas.

Claim 19-20 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. (5,962,215) in view of Sterling et al. (6,312,888 B1)

As to claim 19, Douglas is silent regarding the qualifying optical absorbance feature as having (i.e. an absorbance maximum or an absorbance minimum).

Sterling teaches of optical absorbance feature with (colorant)(i.e. appropriate level)(col. 3, line 17-27) (col. 1, line 25-41).

Therefore it would have been obvious to one having ordinary skill in the art at the time of invention to provide the qualifying optical absorbance feature that have (i.e. an absorbance maximum or an absorbance minimum) for the purpose of providing a more accurate measurement.

As to claims 20 and 24, Douglas is silent regarding wherein the compound comprising a hydrocarbon.

Sterling teaches of hydrocarbon (i.e. a dye or pigment)(col. 9, line 66-67). Thus, it would have been obvious to one having ordinary skill in the art at the time of invention to provide compound that comprises a hydrocarbon (i.e. a dye or pigment) for the purpose of providing a more accurate measurement and detection.

As to claims 25 and 26, Douglas also discloses wherein the identification medium comprising a bar code and magnetic strip (col. 24, 43-48)

Claims 22, 23 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. (5,962,215) in view of Sterling et al. (6,312,888 B1) and further in view of Jina et al. (5,526,120).

As to claims 22, 23 and 27-30, Douglas when modified by Sterling is silent regarding wherein the identification key structure is a physical shape.

Jina teaches of an identification key (56/60) structure with a physical shape (figs. 1, 4-12)(col. 6, line 40-43)(col. 12, line 12-col. 14, line 1-5). Therefore it would have been obvious to one having ordinary skill in the art at the time of invention to provide identification key structure that has a physical shape for the purpose of providing a more accurate calibration and detection

### **Additional Prior Art**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references listed in the attached form PTO-892 teach of other prior art sample element that may anticipate or obviate the claims of the applicant's invention.

### ***Response to Arguments***

Applicant's arguments see pages 10-12, filed on 21 September 2007, with respect to cited references Sterling, Jina and Douglas that the references do not disclose as claimed in independent claims 1, 9, 14, 31 and 42 have been fully considered and are not persuasive.

In response to Applicant's arguments regarding amended claim 1, it is respectfully pointed out to applicant that this argument is not persuasive as Sterling clearly disclose identifying compound that is based on a sample element parameter (i.e. reflectivity, transmissivity) that affects the accuracy of analyte concentration readings in (pars. 0011, 0092) and thus meet the limitations.

Further, In response to Applicant's arguments that Jina is incorrect because Jina teaches a "detectable means" 58/62 for ascertaining proper orientation and/or insertion of a test strip in a meter, not a physical property of the test strip and qualifying sample element, it is respectfully pointed out to applicant that this arguments are not persuasive as Jina clearly disclose in (col. 12, line 46-67) and shows in (figs. 1, 4, 4a and 5: 56,58, 62)(figs. 1, 4, 4a and 5: 10, 46 and 60) these limitations.

Finally, Applicant argues that Douglas does not teach an "identification key" and that Douglas teaches away from the limitation that the identification key is "located...in an optical path for analyte measurement". However this argument is not persuasive since as clearly disclosed in and shown in detail above these limitations as claimed.

### ***Conclusion***

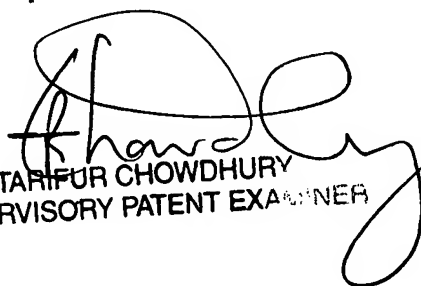
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isiaka Akanbi whose telephone number is (571) 272-8658. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tarifur R. Chowdhury can be reached on (571) 272-2287. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isiaka Akanbi

September 29, 2007

  
TARIFUR CHOWDHURY  
SUPERVISORY PATENT EXAMINER